



PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q92242

Hee-Jong SHIN, et al.

Appln. No.: 10/563,972

Group Art Unit: Unknown

Confirmation No.: 7325

Examiner: Unknown

Filed: January 6, 2006

For: SOLID DISPERSION OF TACROLIMUS

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §§ 1.97 and 1.98

MAIL STOP AMENDMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

- 1. U.S. Patent No. 6,346,537 B1 issued February 12, 2002, to Hata et al.
- 2. European Patent Application No. 0 184 162 A2 published June 11, 1986, to Fujisawa Pharmaceutical Co., Ltd. This application corresponds to U.S. Patent No. 5,110,811.
- 3. U.S. Patent No. 5,110,811 A issued May 5, 1992, to Okuhara et al.
- 4. Japanese Patent Application No. 62-277321 published December 2, 1987, to Fujisawa Pharmaceutical Co., Ltd., with English Abstract. This application corresponds to U.S. Patent No. 4,916,138.
- 5. U.S. Patent No. 4,916,138 issued April 10, 1990, to Ueda et al.
- 6. Korean Patent Application No. 2001-0006070 A published January 15, 2001, to Fujisawa Pharmaceutical Co., Ltd. This application corresponds to U.S. Patent No. 6,316,473.

SHIN et al.

Appln. No. 10/563,972

INFORMATION DISCLOSURE STATEMENT

7. U.S. Patent No. 6,316,473 B1 issued November 13, 2001, to Shimojo et al.

8. Korean Patent Application No. 2003-0040556 A published May 22, 2003, to Fujisawa Pharmaceutical Co., Ltd. This application corresponds to U.S. Patent No.

6,440,458.

9. U.S. Patent No. 6,440,458 B1 issued August 27, 2002, to Yamashita et al.

One copy each of References 2, 4, 6 and 8 above is submitted herewith.

The present Information Disclosure Statement is being filed: (1) No later than three

months from the application's filing date; (2) Before the mailing date of the first Office Action

on the merits (whichever is later); or (3) Before the mailing date of the first Office Action after

filing a request for continued examination (RCE) under §1.114, and therefore, no Statement

under 37 C.F.R. § 1.97(e) or fee under 37 C.F.R. § 1.17(p) is required.

The submission of the listed documents is not intended as an admission that any such

document constitutes prior art against the claims of the present application. Applicant does not

waive any right to take any action that would be appropriate to antedate or otherwise remove any

listed document as a competent reference against the claims of the present application.

The USPTO is directed and authorized to charge all required fees, except for the Issue

Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any

overpayments to said Deposit Account.

Respectfully submitted,

Registration No. 53,892

Sunhee Lee

SUGHRUE MION, PLLC

Telephone: (202) 293-7060

Facsimile: (202) 293-7860

WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: April 7, 2006

2

Substitute for Form 1449 A & B/PTO		Complete if Known				
			Application Number	10/563,972		
<u>INFO</u>	RMATION	DISCLO	SUR	E OV	Confirmation Number	7325
STAT	EMENT BY	Y APPLI	CAN'	^\	Filing Date	January 06, 2006
		-	13 '		First Named Inventor	Hee-Jong SHIN
(use as many sheets as necessary)			Art Unit	Unknown		
			Examiner Name	Unknown		
Sheet	1	of	1		Attorney Docket Number	Q92242
			1	WOFFICE TO	<u> </u>	

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No.1	Document	Number	Publication Date	Name of Patentee or Applicant of Cited Document	
		Number	Kind Code ² (if known)	MM-DD-YYYY		
		US 4,91 <u>6,1</u> 38		04-10-1990	Ueda et al.	
		US 5,110,811	Α	05-05-1992	Okuhara et al.	
		US 6,316,473	B1	11-13-2001	Shimojo et al.	
		US 6,346,537	B1	02-12-2002	Hata et al.	
		US 6,440,458	B1	08-27-2002	Yamashita et al.	
		US			·	
		US				
		US				
		US				

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No.1		Foreign Patent Docur	nent	Publication Date MM-DD-YYYY	Name of Patentee or	Translation ⁶
		Country Code ³	Number ⁴	Kind Code ⁵ (if known)		Applicant of Cited Document	
		EP	0 184 162	A2	06-11-1986	Fujisawa Phamaceutical Co., Ltd.	
		JP	62-277321	Α	12-02-1987	Fujisawa Phamaceutical Co., Ltd.	Abstract
		KR	2001-0006070	Α	01-15-2001	Fujisawa Phamaceutical Co., Ltd.	
		KR	2003-0040556	A	05-22-2003	Fujisawa Phamaceutical Co., Ltd.	
	-						
				<u> </u>			• •
,							
				↓			
					,		
			<u> </u>				

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	include name of the action (in City 11/15 Dot 1 Dita), the article (when appropriate), the of the item (book, magazine				
			<u> </u>		

Examiner Signature		Date Considered	
	· · · · · · · · · · · · · · · · · · ·		· · · · · · · · · · · · · · · · · · ·

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²See Kind Codes of USPTO Patent Documents at www.uspto.gov, MPEP 901.04 or in the comment box of this document. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to indicate here if English language Translation is attached.